

Message Text

UNCLASSIFIED

PAGE 01 STATE 229641
ORIGIN HEW-06

INFO OCT-01 ARA-15 EUR-12 ISO-00 OES-09 EB-08 COME-00
/051 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:VO
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
ARA/AND/V:WSERGEANT
ARA/MEX:PSTORING
ARA/PAN:GBROWN
EUR/NE:HWOOLFLEY
ARA/CEN: JDAVIS
ARA/CEN:AWILSON
ARA/CEN:LPFEIFLE

-----082062 112125Z /64

P 112013Z SEP 78
FM SECSTATE WASHDC
TO AMEMBASSY CARACAS PRIORITY
AMEMBASSY MEXICO PRIORITY
AMEMBASSY PANAMA PRIORITY
AMEMBASSY LONDON PRIORITY
AMEMBASSY SAN JOSE PRIORITY
AMEMBASSY SAN SALVADOR PRIORITY
AMEMBASSY GUATEMALA PRIORITY

UNCLAS STATE 229641

E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, VE, MX, PN, UK, CS, ES, GT

SUBJECT: FDA ADVISORY - FIRM INITIATED RECALL (V-I35-8)

1. FDA ADVISES OF THE FOLLOWING FIRM INITIATED RECALL:
PRODUCT INVOLVED - SODIUM SULFATHIAZOLE (NO STRENGTH SHOWN
ON LABEL) PACKAGED IN 2 OZ., 8 OZ., 1 LB., 5 LB., AND OTHER
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SIZES ON SPECIAL ORDER AS A GRANULAR POWDER FOR ORAL ADMINI-
STRATION TO HONEYBEES; SODIUM SULFATHIAZOLE PACKAGED IN 1 LB.
AND 5 LB. SIZES AS WELL AS OTHER SIZED ON SPECIAL ORDER AS
A MICROFINE POWDER FOR ORAL ADMINISTRATION TO HONEYBEES.

2. PRODUCT IDENTIFICATION: (A) THE PRODUCTS ARE MARKETED
UNDER THE GENERIC NAME (SODIUM SULFATHIAZOLE, BOTH GRANULAR,

CATALOG 36), AND MICROFINE, CATALOG 363) AND LABELED AS
PACKED BY WALTER T. KELLEY CO., CLARKSON, KY 42726 (B) ALL
PRODUCT SHIPPED SINCE 7/1/77 - 2 DIGIT LOT NUMBERS MAY APPEAR
ON THE LABEL AND SOME LABELS MAY BE UNCODED.

3. MANUFACTURER/RECALLING FIRM: WALTER T. KELLEY CO.,
CLARKSON, KY 42726 (REPACKER AND RECALLING FIRM)

4. REASON FOR RECALL RECOMMENDATION: THE PRODUCT IS A
NAD (NEW ANIMAL DRUG) FOR WHICH THE FIRM DOES NOT HAVE
AN APPROVED NADA (NEW ANIMAL DRUG APPLICATION). THE FIRM
WAS ADVISED OF THE NEW DRUG STATUS IN AN INFORMATION LETTER
DATED 6/23/77. DURING THE EI OF 5/9-10 AND 15/78 FIRM'S
MANAGEMENT INDICATED THAT THEY WERE CONSIDERING RECALLING
PRODUCT DISTRIBUTED SINCE 7/1/77. RECALL LETTERS WERE
MAILED MAY 17, 1978.

5. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO
DETERMINE IF THEY HAVE RECEIVED RECALL LETTERS. QUESTIONS
REGARDING RECALL SHOULD BE REFERRED TO WALTER T. KELLEY, CO.

6. FOREIGN CONSIGNEES AS SUPPLIED BY FIRM TO FDA ARE:

PROFESSOR M. STEJSKAL, NUCLEO DE MONAGAS, ESCUELA DE
ZOOTECNIA, CENTRO DE INVESTIGACIONES, JUSEPIN, VENEZUELA

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SR. CARLOS SANCHEC, NINOS HEROES NO. 86 OTE, HERMOSILLO -
SONORA, MEXICO

REP. DE PANAMA, MINISTERIS DE DESARROLLO, ARGOPECUARIC,
RAMON VANGEAS-A PORTAGO 5390, PANAMA, REPUBLIC OF PANAMA

A. TAYLOR, DUNGRIANACH, MUNLOCHY, ROSS-SHIRE, SCOTLAND

JACK AWTY, BUNGALOW-BRAMTON ROAD, WOMBWELL, SOUTH YORK-
SHIRE 5730SR ENGLAND

CESAR CHAVIRA O., FCO BARRIENTOS NO. 404, CHEHUAHUA, CHEH,
MEXICO

PAUL C. HARI, LAS JUNTAS DE ABANGARES, GUANACASTE, COSTA
RICA

AUTHOR T. HENDERSON, CONDOMINIO CUSCATLAN, NO. 327/329-4A,
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M.J. WILLIAMS, 84 ASHBUR ROAD, MELBOURNE, DERBY ENGLAND

WALTER LOUIS NETTLEHURST JOCOTON CHIQUIMULA, GUATAMALA,
CENTRAL AMERICA. CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUG RECALL
Control Number: n/a
Copy: SINGLE
Draft Date: 11 sep 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE229641
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:VO
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780370-0214
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780980/aaaacooo.tel
Line Count: 118
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 7c91e852-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1482796
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - FIRM INITIATED RECALL (V-I35-8)
TAGS: OGEN, ETRD, EIND, TBIO, VE, MX, PN, UK, CS, ES, GT
To: CARACAS MEXICO MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/7c91e852-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014